

## **Remarks**

Applicants wish to thank the Examiner for the allowance of claims 17, 19-21, 26-29, 31, 32, 34-36, 41, and 42. Claims 17, 19, and 29 have been amended to correct formalities. There have been no substantive changes to the claims which have been allowed. Claims 33, and 38-40 have been amended to more clearly define the invention. New claims 43, 44, and 45 have been introduced. Claim 43 is supported by page 4, third paragraph of the specification as originally filed. Claims 44 and 45 are supported by the paragraph bridging pages 8 and 9 of the specification as originally filed. No new matter has been introduced.

Also, the finality of the Office Action is premature because the rejection of claims 38-40 as being subject to a restriction requirement is being presented for the first time in the prosecution. Accordingly, Applicants should be allowed to rebut this rejection and respectfully request that the finality of the Office Action be removed.

In view of the foregoing amendments and the following remarks, reconsideration of the present patent application is respectfully requested.

### **Rejection of claims 38-40**

Claims 38-40 are rejected to because the Examiner alleges that claims 38-40 are not so linked as to form a single inventive concept. Further the Examiner alleges that the compositions of claims 38-40 are so diverse in scope that a prior art anticipating one composition under 35 USC §102 would not render obvious another compound of the same claim under 35 USC §103. Also, in a phone conversation with the Examiner, Applicants were told that the combinations were separately patentable from the allowed compound claims and subject to a restriction requirement. Applicants respectfully traverse.

Applicants have amended claims 38-40 to more clearly define the combinations. Claims 38-40 are directed to pharmaceutical compositions comprising a combination of compounds of allowed claims with either a steroid, a dopamine receptor agonist or an anticholinergic or antimuscarinic agent.

Under MPEP §806.05(c) in order to establish that combinations and subcombination inventions are distinct, two-way distinctness must be demonstrated. To support a requirement for restriction, both two-way distinctness and reasons for insisting on restriction are necessary, i.e. separate classification, status or field of search. See MPEP §808.02.

The inventions are distinct if it can be shown that a combination as claimed:

- (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and
- (B) the subcombination can be shown to have utility either by itself or in other and different relations.

In the present case with respect to dependent claims 38-40, the novel compounds of the present invention from which claims 38-40 depend from are a subcombination of the combination recited in claims 38-40. The particulars of this subcombination are required for patentability. Therefore, because they are a subcombination required for the patentability of the combination the elements necessary for distinctness have not been met. Accordingly, the requirement to withdraw claims 38-40 because they are not so linked as to form a single inventive concept is incorrect and Applicants respectfully request that the rejection and restriction of claims 38-40 be withdrawn.

#### Rejection under 35 U.S.C. §112

Claim 33 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse.

With regard to the objection to claim 33, the results of the guinea pig tracheal strip assay and the cAMP level assay in cells expressing the beta-2 adrenoreceptor, given on page 15 of the specification, show that the instant compounds have good beta-2 adrenoreceptor activity, i.e. they are good activators of the beta 2- adrenoreceptor. It is perfectly rational to conclude from these results that the compounds are effective in the treatment of any condition which is mediated by activation of the beta 2 -adrenoreceptor. In answer to the Examiner's quotation from *Brenner v. Manson*, no guessing is required on the part of those skilled in the art, and the usefulness of the instant compounds is not indicated in a meaningless way. On the contrary, the usefulness of the compounds is defined in a wholly meaningful way as the treatment of a condition alleviated by activation of the beta 2-adrenoreceptor. The identification of such conditions requires no guessing by those skilled in the art. Such conditions are well known and include the inflammatory or obstructive airways diseases specified on pages 15-16 and the other conditions mentioned on page 16, last paragraph. The conditions to be treated by the instant compounds are defined by reference to a clearly defined and determinable characteristic, i.e. "alleviated by activation of the beta 2-adrenoreceptor" which is wholly in line with the measured properties of the compounds.

In view of the remarks and the amendments, further and favorable consideration of the present application and the allowance of all pending claims are respectfully requested. The Examiner is also invited to contact the undersigned should the Examiner believe that such contact would expedite prosecution of the present application.

Respectfully submitted,

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